K090618
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510(K) Summary

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	George Cho Senior Vice President of Medical Technology and Regulatory Affairs
Date Summary Prepared:	March 6, 2009
Device Trade Name:	Cynosure SmartCool family cold air device
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser Class II (21 CFR 878.4810)
Equivalent Device:	Cryo 5 (K040727), Cryo V6 (K060395), and CryoMini (K080735)
Device Description:	The SmartCool family cold air device consists of a refrigeration unit that creates cold air. The cold air is blown onto the skin using an air hose.
Intended Use:	The SmartCool family cold air device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief.
Comparison:	The SmartCool family cold air device has the same indications for use, the same principle of operation, and the same performance as the predicate device(s).
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The SmartCool family cold air device is a safe and effective device for the 'indications for use' specified.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2009

Cynosure, Inc.
% Mr. George Cho
Senior Vice President of Medical
Technology and Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts 01886

Re: K090618
Trade/Device Name: Cynosure SmartCool Family Cold Air Device: SmartCool, SmartCool 6, and Cryo C
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 6, 2009
Received: March 9, 2009

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Cynosure SmartCool Family Cold Air Device: SmartCool, SmartCool 6, and Cryo C.

Indications For Use:

The SmartCool family cold air device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief.

Prescriptive Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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